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54 Syringe.

57 The invention relates to a syringe comprising an
 ampoule having a plunger and a sealing stopper,
 and a needle holder comprising a collar, a neck for
 an injection needle, a shaft between the collar and
 the neck and a by-pass means in the inner wall of
 the shaft, the rear face of the sealing stopper com-
 prising a plurality of recesses or spacing supports
 which are provided in or on the circumferential edge
 of the sealing stopper.

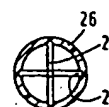
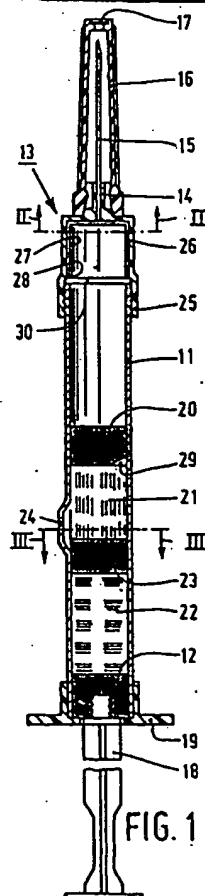


FIG. 2

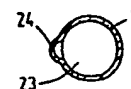


FIG. 3



FIG. 4

EP 0 340 880 A2

SYRINGE

This patent application is a divisional application of copending European patent application 86200983.4.

The invention relates to a syringe, comprising:

- a hollow, substantially cylindrical ampoule which is open at both ends,
- a plunger which is movable in the ampoule and seals said ampoule and to which a plunger rod is connectable,

- a substantially rotationally symmetrical sealing stopper having dimensions such that the sealing stopper can be provided in a sealing manner in said ampoule and so as to be movable in the ampoule,

- if desired, a separating stopper provided in the ampoule in a sealing manner so as to be able to keep two different substances, if present in the ampoule, separated from each other prior to use of the syringe,

- in case two different substances are present in the ampoule, an ampoule by-pass means formed in the wall of the ampoule, which by-pass means has a length at least as great as that of said separating stopper and through which by-pass means, during use of the syringe, liquid behind the separating stopper can reach the substance in front of the separating stopper and can mix with said substance or can dissolve it, but which by-pass means, prior to use of the syringe, is sealed from the liquid behind said separating stopper by means of the separating stopper.

- a finger grip or means for the connection thereof to the outside of the ampoule, and

- a needle holder comprising:

- (a) a collar connected to the front end of the ampoule in a sealing manner,

- (b) a neck for sealingly attaching an injection needle, optionally covered by a needle guard to keep the needle in a sterile condition,

- (c) a hollow, substantially cylindrical shaft disposed between the collar and the neck, the shaft being proportioned so that the space bounded by the inner wall of the shaft and the rear face of the neck has a slightly larger circumference than the inner wall of the ampoule and is at least longer than the sealing stopper, and

- (d) a needle holder by-pass means in the inner wall of the shaft through which injection liquid behind the sealing stopper can reach the injection needle when, upon using the syringe, the sealing stopper is moved forward into the shaft of the needle holder.

Syringes, intended for the sequential injection of two or more different injection liquids which may

not be in contact with each other for a longer period of time, are known from United States Patent Specifications 4,439,184 and 4,496,344, and are the subject of the European patent application 86200983.4, mentioned before.

In case the syringe of the invention is intended for separate storage of two different substances, such a syringe may accommodate two injection liquids. However, the use is not restricted hereto. The same syringe can also be used equally successfully to accommodate a solid medicament in the space between the sealing stopper and the separating stopper and a diluent or solvent therefor in the space behind the separating stopper. Such a syringe provides a great extent of flexibility so that the syringe can be used without any adapting means both for accommodating two or more different injection liquids and for accommodating a solid medicament and a solvent or diluent for said medicament. In particular for this application the use of a needle guard with bacteria filter offers the advantage, that during the operation of dissolving the solid medicament in the solvent the syringe remains sterile, because the needle guard does not need to be removed beforehand. Such a two-chamber syringe can be filled very simply by first providing the sealing stopper and then providing, in a vertical position, successively the first injection liquid, the separating stopper, the second injection liquid, and finally the plunger. Of course, the reverse sequence is equally possible. After providing the needle holder comprising or not comprising an injection needle, preferably covered by a needle guard, and the finger grip, the syringe is ready for delivery to the customer. This filling procedure presents the opportunity to accommodate without any problems a freeze-dried medicament in the front compartment and a solvent or diluent for said medicament in the rear compartment.

The by-pass means for the injection liquid in the shaft of the needle holder may be constructed in various manners, for example, as described in the above-mentioned United States Patent Specification 4,496,344. At least one slot is preferably recessed in the inner wall of the shaft of the needle holder which extends in the longitudinal direction of the shaft over a length which is slightly larger than the length of the sealing stopper and which adjoins at least one slot, radially recessed in the rear face of the neck and communicating with the rear aperture of the needle. In another preferred embodiment the inner wall of the shaft of the needle holder comprises at least one inwardly projecting ridge which extends in the longitudinal direction of the shaft over a length which is slightly larger than

the length of the sealing stopper, and the front face of the sealing stopper or the rear face of the neck of the needle holder comprises a few spacing supports, so that during use of the syringe the sealing stopper is deformed by contact with the ridge or ridges, a passage being formed for the injection liquid behind the sealing stopper allowing the injection liquid to reach the injection needle past the said stopper. In this latter preferred embodiment the spacing supports, if they are provided on the rear face of the neck of the needle holder, constitute preferably one or more ridges which extend(s) radially on said rear face as a continuation of the ridge or ridges on the inner wall of the shaft. In again another preferred embodiment the inner wall of the shaft of the needle holder has a circular or oval cross-section and the front face of the sealing stopper or the rear face of the neck of the needle holder comprises a few spacing supports, the space bounded by the inner wall of the shaft and the rear face of the neck of the needle holder or the spacing supports on the said rear face, respectively, having a larger circumference than the expanded sealing stopper and being slightly longer than the sealing stopper or the sealing stopper including the spacing supports, respectively. In this way the sealing stopper, in its foremost position within the shaft of the needle holder, can fill the said space substantially entirely, but an opening remains around said stopper. In still another embodiment the by-pass means for the injection liquid in the shaft of the needle holder may be constructed as described in Netherlands Patent Application 8500341. In this embodiment the by-pass means is constructed as a duct recessed in the side wall of the shaft and adjoining the needle holder neck on the outside of the front end wall of the shaft, an aperture being recessed in the front end of the shaft. When using the syringe, air present in front of the sealing stopper can escape through said aperture so that the injection can be administered directly without de-aerating the syringe, the so-called "pique-directe" method.

The by-pass means in the wall of the ampoule may also be constructed in various manners. The ampoule may be made of glass or of a suitable synthetic material; in the latter case the ampoule may be manufactured, for example, by injection moulding. When the ampoule is made of synthetic material the by-pass means in the wall of the ampoule preferably consists of at least one groove recessed in the inner wall of the ampoule and extending in the longitudinal direction of the ampoule over a length which is slightly larger than the length of the separating stopper or the collective separating stoppers. In another preferred embodiment the inner wall of the ampoule at the area of the by-pass comprises at least one ridge which

extends in the longitudinal direction of the ampoule over a length which is slightly larger than the length of the separating stopper or the collective separating stoppers, so that the separating stopper or stoppers, during use of the syringe, is/are deformed by contact with the ridge or ridges, a passage for the liquid behind the separating stopper of stoppers being formed through which the liquid can pass said stopper or stoppers. Such by-pass means may also be made in a glass ampoule wall, but synthetic materials are better suited for this purpose. A glass ampoule is by far to be preferred to a synthetic material ampoule because no diffusion of air oxygen to the substances accommodated in the ampoule can occur through the glass wall so that oxidative decomposition of the said substances is avoided. Moreover, synthetic materials are generally less suitable than glass to store therein for a longer period of time liquids destined for injection, because synthetic materials can contaminate the liquids or can adversely influence the stability of the said liquids. In a glass ampoule, the wall of the ampoule can most simply be provided with a by-pass means by deforming the wall of the ampoule at the area of the by-pass over a length which is slightly larger than the length of the separating stopper or collective separating stoppers, so that, upon use of the syringe, the liquid behind the separating stopper or stoppers can pass said stopper or stoppers at the area of the deformation. Such a deformation of the ampoule wall may be in the form as shown in the United States Patent Specification 2,717,601 mentioned hereinbefore. For example, the local deformation of the ampoule wall consists preferably of at least one outwardly projecting longitudinal bulge of the ampoule wall, so that upon use of the syringe, the liquid behind the separating stopper or stoppers can reach the substance in front of the separating stoppers or front separating stopper, or of at least one inwardly projecting longitudinal bulge of the ampoule wall so that, upon use of the syringe, the separating stopper or stoppers is/are deformed by contact with the inwardly projecting bulge or bulges, a passage for the liquid behind the separating stopper or stoppers being formed allowing the liquid to reach the substance in front of the separating stopper or front separating stopper past said stopper or stoppers. The ampoule wall may also be deformed locally in such way that the ampoule has an oval cross-section at that area so that, upon use of the syringe, the liquid behind the separating stopper or stoppers can reach the substance in front of the separating stopper or front separating stopper.

A local deformation of the wall of the ampoule in the form of one or more outwardly projecting longitudinal bulges is generally considered to be the best suitable solution for a by-pass means in

the glass ampoule wall, because it can be very simply provided in an ampoule wall and, upon use of the syringe, forms a reliable passage for the liquid. The needle holder provided with a collar ensures, together with the finger grip, that such a bulge or such bulges in the glass ampoule wall is/are protected from damage or fracture. For example, when the syringe is dropped on a table or on the floor, it will now in most of the cases land on the needle holder collar and finger grip projecting beyond the ampoule wall, so that the bulge in the ampoule wall cannot contact the table or the floor. Moreover, packaging such syringes is easier, and during transport of the packaged syringes fractures will less easily occur due to the protecting influence of the needle holder collar and the finger grip. A syringe without a needle holder, as described in the United States Patent Specification 2,717,601 mentioned hereinbefore lacks such a protection of the by-pass means in the glass wall of the ampoule. It will be obvious that the invention relates more in particular to pre-fillable or pre-filled syringes, i.e. syringes which can be filled by the customer or supplier ample time before use.

The components of the syringe, such as ampoule, needle guard, finger grip and plunger rod, can be connected in the usual manner, for example, by means of a screwed joint, bayonet or snap-cap connection. The injection needle is preferably covered by a needle guard to keep the needle in a sterile condition. In case the injection needle is supplied separately, the needle holder neck is preferably constructed externally as a cone, for example, a Luer cone or Luer lock cone, around which the needle comprising a needle sleeve can be connected in a fitting manner. Usually said neck is sealingly provided with a detachable cap to keep the contents of the syringe sterile before use. Said cap is preferably also provided with a bacteria filter to keep the syringe sterile even during and after the mixing operation. Needle holder, finger grip and plunger rod are preferably manufactured from a suitable non-deformable synthetic material, the stoppers from a suitable resilient material, preferably rubber of a pharmaceutical quality.

For administering an injection it is common practice to find out whether the tip of an injection needle is present at the correct place in the patient's body, i.e. whether or not in a bloodvessel. Therefore, the plunger is usually slightly retracted by means of the plunger rod, body fluid or no body fluid, respectively, reaching the ampoule via the needle duct: the so-called nurse-aspiration. When the ampoule is manufactured from a transparent material, the user of the syringe can ascertain whether the tip of the injection needle is in a vein, if so desired, and whether hence the injection liquid will or will not be injected directly into the blood

stream. During said nurse-aspiration the sealing stopper is not allowed to be retracted together with the plunger, because as a result of this the passage to the ampoule could be obstructed so that no body fluid could reach the ampoule.

According to the invention it has now been found that said nurse-aspiration can take place without any hindrance when three conditions are satisfied, namely: (1) when the shaft of the needle holder has a slightly larger inner circumference than the inner wall of the ampoule, (2) when the rear face of the sealing stopper comprises a plurality of recesses or spacing supports provided in or on the circumferential edge of the sealing stopper, and (3) when, in case of recesses provided in the rear face of the sealing stopper, a circumferential groove is recessed in the backmost portion of the shaft of the needle holder adjoining the ampoule. As a result of this, body fluid can be drawn into the ampoule with no hindrance during the above-described nurse-aspiration.

Since the needle holder shaft is slightly wider than the inner wall of the ampoule, the sealing stopper cannot be drawn into the ampoule during nurse-aspiration and thus obstruct the passage for body fluid. In the case of spacing supports on the circumferential edge of the rear face of the sealing stopper, the sealing stopper is slightly retracted during aspiration until the spacing supports bear against the front inner edge of the inner wall of the ampoule and prevent further retraction of the sealing stopper; body fluid can now reach the ampoule via the bypass means in the shaft and across the spacing supports. In the case of recesses in the rear face of the sealing stopper, said stopper is retracted slightly during aspiration till against the front inner edge of the ampoule; body fluid can now reach the ampoule via the by-pass means in the shaft, the circumferential groove in the shaft and the recesses in the sealing stopper. It will be obvious that this provision can be used in all syringes provided they comprise a needle holder having a shaft which comprises a by-pass means for injection liquid and which, upon use of the syringe, can accommodate the sealing stopper.

The invention will now be described in greater detail with reference to an embodiment which is shown in the drawings, in which:

Figure 1 is a longitudinal sectional view of a syringe according to the invention in the condition in which it can be transported and stored;

Figures 2 and 3 are cross-sectional views through the needle holder and ampoule respectively of the Figure 1 syringe, taken on the lines II-II and III-III viewed in the direction of the needle and of the plunger, respectively; and

Figure 4 is a bottom view of the sealing stopper of the Figure 1 syringe, viewed in the direction of the injection needle.

The syringe shown in Figure 1 comprises an ampoule 11, in which at one end a plunger 12 is provided while the other end comprises a needle holder 13 in the neck 14 of which an injection needle 15 is connected. The injection needle is covered in a sterile manner by a needle guard 16 which at its front comprises an aperture with a bacteria filter 17. The plunger can be moved by means of a plunger rod 18 which is connected to the plunger, for example, by means of a screwed joint. At the same end where the plunger is present, the ampoule comprises on its outside a finger grip 19 which is connected around the ampoule according to the so-called snap-cap principle. The ampoule is preferably manufactured from glass, the finger grip preferably from a slightly resilient but non-deformable material, for example, a synthetic material. In another suitable embodiment the finger grip forms one assembly with the ampoule and may then be formed as a flange-like part of the ampoule projecting radially outwards.

Instead of a needle guard with bacteria filter, a needle guard which is closed entirely at its front end may alternatively be used. The use of a needle guard with bacteria filter is to be preferred, however, because in this case the needle can remain protected in a sterile manner for a longer period of time, namely during mixing and de-aerating. Moreover the syringe then may be stored an additional period after the mixing or making ready for use operation before it is actually used.

A sealing stopper 20 is present in the part of the ampoule remote from the plunger at a considerable distance from the open end of the ampoule. Two different liquids 21 and 22 which are kept separated from each other by a separating stopper 23 are present in the ampoule between the plunger and the stopper. The stoppers are manufactured from rubber of a pharmaceutical quality. The ampoule furthermore comprises a by-pass means for the injection liquid in the form of a longitudinal bulge 24 in the glass wall, as a result of which a longitudinal slot-shaped aperture is formed. This slot-shaped aperture terminates at its rear end near separating stopper 23, so that the injection liquids in the stored condition of the syringe cannot reach each other.

The by-pass means in the ampoule wall may also be constructed differently. For example, the glass wall may locally be bent inwards longitudinally, so that internally at the area of the passage a longitudinal ridge is formed in the ampoule. The said ridge can cause the separating stopper to be deformed upon contacting, so that on either side of

the ridge passages for the liquid are formed. Of course, two or more slot-shaped apertures or ridges may also be present. The wall of the glass ampoule at the area of the by-pass may also have an oval cross-section allowing liquid to pass the stopper in the passage.

The needle holder 13 comprising a neck 14 is connected to the ampoule by means of a collar 25. A shaft 26 is present between the neck and the collar. The needle holder is preferably manufactured from a slightly resilient material which, however, has sufficient non-deformability, for example, a suitable synthetic material, and is connected to the front end of the ampoule by means of a so-called snap-cap connection. In another embodiment the needle holder may be connected to the ampoule by means of a screwed or a bayonet connection, or, when the ampoule also comprises a collar or a flange, by means of a clamping ring. Four slots 27 are recessed in the inner wall of the shaft and the rear face of the neck and the rear face of the neck and communicate with the injection needle. The collective cross-section of the slots should at least be as large as that of the duct in the injection needle. The shaft of the needle holder is constructed in such way that when the sealing stopper is moved forward axially, it is received by the shaft in a sliding manner. The inner wall of the shaft, therefore, has a slightly larger circumference than the inner wall of the ampoule; however, this circumference may not be larger than the circumference of the sealing stopper in the expanded condition. The inner wall of the shaft is slightly longer than the length of the sealing stopper so that the part 28 of the slots adjoining the ampoule is uncovered when the sealing stopper is moved in its extreme forward position to against the rear face of the neck of the needle holder. In order to be able for nurse-aspiration, the rear face of the sealing stopper comprises three notches 29 (see also figure 4) which are recessed in the circumferential edge of the sealing stopper, while a circumferential groove 30 which communicates with the slots 27 in the shaft of the needle holder is recessed in the part of the shaft of the needle holder adjoining the ampoule. The operation of these provisions upon nurse-aspiration has been explained already hereinbefore.

The use of the syringe according to the invention is described in parent application EP 86200983.4. Nurse-aspiration may be carried out, if desired, the notches 29 recessed in the circumferential edge of the rear face of the sealing stopper 20 ensuring that the admission of body fluid to the ampoule cannot be obstructed when during said nurse-aspiration the sealing stopper is slightly retracted into the shaft of the needle holder.

Claims

1. A syringe, comprising:

- a hollow, substantially cylindrical ampoule which is open at both ends,
 - a plunger which is movable in the ampoule and seals said ampoule and to which a plunger rod is connectable,
 - a substantially rotationally symmetrical sealing stopper having dimensions such that the sealing stopper can be provided in a sealing manner in said ampoule and so as to be movable in the ampoule,
 - if desired, a separating stopper provided in the ampoule in a sealing manner so as to be able to keep two different substances, if present in the ampoule, separated from each other prior to use of the syringe,
 - in case two different substances are present in the ampoule, an ampoule by-pass means formed in the wall of the ampoule, which by-pass means has a length at least as great as that of said separating stopper and through which by-pass means, during use of the syringe, liquid behind the separating stopper can reach the substance in front of the separating stopper and can mix with said substance or can dissolve it, but which by-pass means, prior to use of the syringe, is sealed from the liquid behind said separating stopper by means of the separating stopper,
 - a finger grip or means for the connection thereof to the outside of the ampoule, and
 - a needle holder comprising:
 - (a) a collar connected to the front end of the ampoule in a sealing manner,
 - (b) a neck for sealingly attaching an injection needle, optionally covered by a needle guard to keep the needle in a sterile condition,
 - (c) a hollow, substantially cylindrical shaft disposed between the collar and the neck, the shaft being proportioned so that the space bounded by the inner wall of the shaft and the rear face of the neck has a slightly larger circumference than the inner wall of the ampoule and is at least longer than the sealing stopper, and
 - (d) a needle holder by-pass means in the inner wall of the shaft through which injection liquid behind the sealing stopper can reach the injection needle when, upon using the syringe, the sealing stopper is moved forward into the shaft of the needle holder,
- said syringe being characterized in that
- the rear face of the sealing stopper comprises a plurality of recesses which are provided in the circumferential edge of the sealing stopper, and
 - a circumferential groove is recessed in the backmost portion of the shaft of the needle holder adjoining the ampoule.

2. a syringe, comprising:

- a hollow, substantially cylindrical ampoule which is open at both ends,
 - a plunger which is movable in the ampoule and seals said ampoule and to which a plunger rod is connectable,
 - a substantially rotationally symmetrical sealing stopper having dimensions such that the sealing stopper can be provided in a sealing manner in said ampoule and so as to be movable in the ampoule,
 - if desired, a separating stopper provided in the ampoule in a sealing manner so as to be able to keep two different substances, if present in the ampoule, separated from each other prior to use of the syringe,
 - in case two different substances are present in the ampoule, an ampoule by-pass means formed in the wall of the ampoule, which by-pass means has a length at least as great as that of said separating stopper and through which by-pass means, during use of the syringe, liquid behind the separating stopper can reach the substance in front of the separating stopper and can mix with said substance or can dissolve it, but which by-pass means, prior to use of the syringe, is sealed from the liquid behind said separating stopper by means of the separating stopper,
 - a finger grip or means for the connection thereof to the outside of the ampoule, and
 - a needle holder comprising:
 - (a) a collar connected to the front end of the ampoule in a sealing manner,
 - (b) a neck for sealingly attaching an injection needle, optionally covered by a needle guard to keep the needle in a sterile condition,
 - (c) a hollow, substantially cylindrical shaft disposed between the collar and the neck, the shaft being proportioned so that the space bounded by the inner wall of the shaft and the rear face of the neck has a slightly larger circumference than the inner wall of the ampoule and is at least longer than the sealing stopper, and
 - (d) a needle holder by-pass means in the inner wall of the shaft through which injection liquid behind the sealing stopper can reach the injection needle when, upon using the syringe, the sealing stopper is moved forward into the shaft of the needle holder,
- said syringe being characterized in that
- the rear face of the sealing stopper comprises a plurality of spacing supports which are provided on the circumferential edge of the sealing stopper.

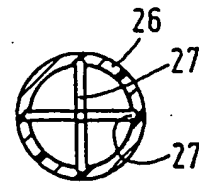
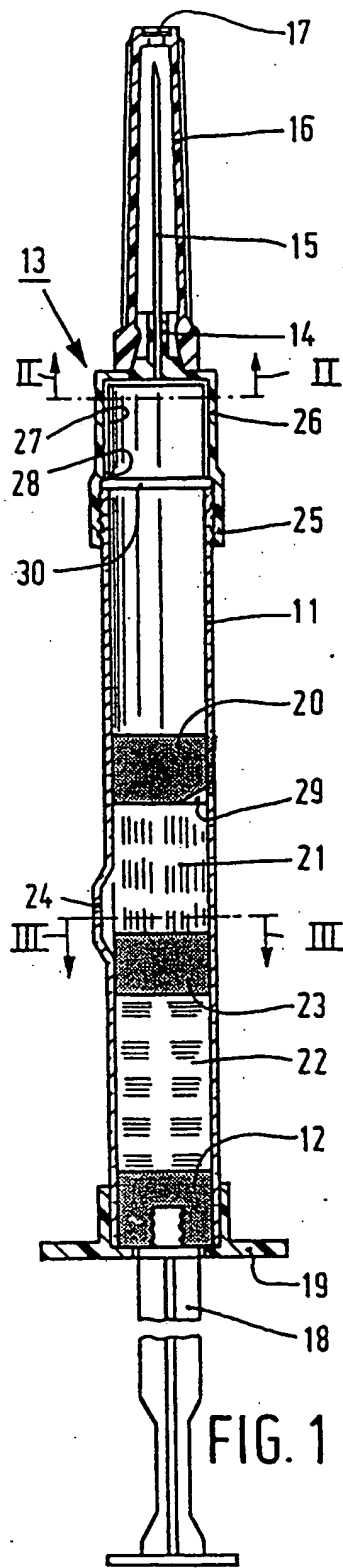


FIG. 2

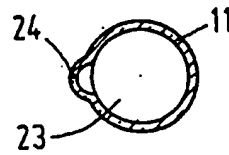


FIG. 3



FIG. 4

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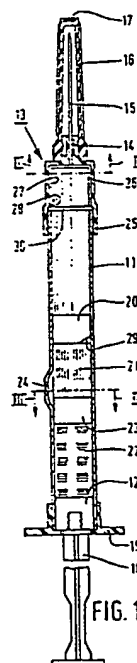
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54 **Syringe.**

57 The invention relates to a syringe comprising an ampoule (11) having a plunger (12) and a sealing stopper (20), and a needle holder (13) comprising a collar, a neck (14) for an injection needle (15), a shaft (26) between the collar (25) and the neck (14) and a by-pass means in the inner wall of the shaft (26), the rear face of the sealing stopper (20) comprising a plurality of recesses (29) or spacing supports which are provided in or on the circumferential edge of the sealing stopper (20).



EP 0 340 880 A3



European Patent
Office

EUROPEAN SEARCH REPORT

Application Number

EP 89 20 1747

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl. 4)
A	GB-A-2 010 681 (N.V. PHILIPS' GLOEILAMPEN FABRIEKEN) * Figures 1-3; abstract *	1	A 61 M 5/28
A,D	EP-A-0 072 058 (DUPHAR INT. RESEARCH B.V.) * Figures; description *	1	
			TECHNICAL FIELDS SEARCHED (Int. Cl. 4)
			A 61 M
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 08-01-1990	Examiner SEDY, R.
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			

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EP 0 340 880 B1

Note : Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid (Art. 99(1) European patent convention).

Description

This patent application is a divisional application of copending European patent application 86200983.4 (EP-A-0207544).

The invention relates to a syringe, comprising:

- a hollow, substantially cylindrical ampoule which is open at both ends,
- a plunger which is movable in the ampoule and seals said ampoule and to which a plunger rod is connectable,
- a substantially rotationally symmetrical sealing stopper having dimensions such that the sealing stopper can be provided in a sealing manner in said ampoule and so as to be movable in the ampoule,
- a finger grip or means for the connection thereof to the outside of the ampoule, and
- a needle holder comprising:

(a) a collar connected to the front end of the ampoule in a sealing manner,

(b) a neck for sealingly attaching an injection needle, optionally covered by a needle guard to keep the needle in a sterile condition,

(c) a hollow, substantially cylindrical shaft disposed between the collar and the neck, the shaft being proportioned so that the space bounded by the inner wall of the shaft and the rear face of the neck has a slightly larger circumference than the inner wall of the ampoule and is at least longer than the sealing stopper, and

(d) a needle holder by-pass means in the inner wall of the shaft through which injection liquid behind the sealing stopper can reach the injection needle when, upon using the syringe, the sealing stopper is moved forward into the shaft of the needle holder.

Syringes, intended for the sequential injection of two or more different injection liquids which may not be in contact with each other for a longer period of time, are known from United States Patent Specifications 4,439,184 and 4,496,344, and are the subject of the European patent application 86200983.4 (EP-A-0207544), mentioned before.

The by-pass means for the injection liquid in the shaft of the needle holder may be constructed in various manners, for example, as described in the above-mentioned United States Patent Specification 4,496,344. At least one slot is preferably recessed in the inner wall of the shaft of the needle holder which extends in the longitudinal direction of the shaft over a length which is slightly larger than the length of the sealing stopper and which adjoins at least one slot, radially recessed in the rear face of the neck and communicating with the rear aperture of the needle. In another preferred embodiment the inner wall of the shaft of the needle holder comprises at least one inwardly

projecting ridge which extends in the longitudinal direction of the shaft over a length which is slightly larger than the length of the sealing stopper, and the front face of the sealing stopper or the rear face of the neck of the needle holder comprises a few spacing supports, so that during use of the syringe the sealing stopper is deformed by contact with the ridge or ridges, a passage being formed for the injection liquid behind the sealing stopper allowing the injection liquid to reach the injection needle past the said stopper. In this latter preferred embodiment the spacing supports, if they are provided on the rear face of the neck of the needle holder, constitute preferably one or more ridges which extend(s) radially on said rear face as a continuation of the ridge or ridges on the inner wall of the shaft. In again another preferred embodiment the inner wall of the shaft of the needle holder has a circular or oval cross-section and the front face of the sealing stopper or the rear face of the neck of the needle holder comprises a few spacing supports, the space bounded by the inner wall of the shaft and the rear face of the neck of the needle holder or the spacing supports on the said rear face, respectively, having a larger circumference than the expanded sealing stopper and being slightly longer than the sealing stopper or the sealing stopper including the spacing supports, respectively. In this way the sealing stopper, in its foremost position within the shaft of the needle holder, can fill the said space substantially entirely, but an opening remains around said stopper. In still another embodiment the by-pass means for the injection liquid in the shaft of the needle holder may be constructed as described in Netherlands Patent Application 8500341. In this embodiment the by-pass means is constructed as a duct recessed in the side wall of the shaft and adjoining the needle holder neck on the outside of the front end wall of the shaft, an aperture being recessed in the front end of the shaft. When using the syringe, air present in front of the sealing stopper can escape through said aperture so that the injection can be administered directly without de-aerating the syringe, the so-called "piqûre-directe" method.

For administering an injection it is common practice to find out whether the tip of an injection needle is present at the correct place in the patient's body, i.e. whether or not in a bloodvessel. Therefore, the plunger is usually slightly retracted by means of the plunger rod, body fluid or no body fluid, respectively, reaching the ampoule via the needle duct: the so-called nurse-aspiration. When the ampoule is manufactured from a transparent material, the user of the syringe can ascertain whether the tip of the injection needle is in a vein, if so desired, and whether hence the injection liquid will or will not be injected directly into the blood stream. During said nurse-aspiration the sealing stopper is not allowed to be retracted together with the plunger, because as a result of this the passage to the ampoule could be obstructed so that no body fluid

could reach the ampoule.

According to the invention it has now been found that said nurse-aspiration can take place without any hindrance when three conditions are satisfied, namely: (1) when the shaft of the needle holder has a slightly larger inner circumference than the inner wall of the ampoule, (2) when the rear face of the sealing stopper comprises a plurality of recesses provided in the circumferential edge of the sealing stopper, and (3) when, a circumferential groove, communicating with the needle holder by-pass means, is recessed in the backmost portion of the shaft of the needle holder adjoining the ampoule. As a result of this, during nurse aspiration, when the sealing stopper is positioned with its rear edge bearing against the front end of the ampoule, the recesses communicate with the circumferential groove, and body fluid can be drawn into the ampoule with no hindrance during the above-described nurse-aspiration.

Alternatively, instead of the recesses a plurality of spacing supports are provided, which extend backwards and are provided on the circumferential edge of the rear face of the sealing stopper, to permit the above nurse-aspiration. Such spacing supports are provided in a mutually spaced position and so proportioned, that during nurse aspiration, when the spacing supports bear against the front end of the ampoule, body fluid can pass the sealing stopper backwards through the needle holder bypass means and the spaces between said supports mutually.

Since the needle holder shaft is slightly wider than the inner wall of the ampoule, the sealing stopper cannot be drawn into the ampoule during nurse-aspiration and thus cannot obstruct the passage for body fluid. In the case of spacing supports on the circumferential edge of the rear face of the sealing stopper, the sealing stopper is slightly retracted during aspiration until the spacing supports bear against the front inner edge of the inner wall of the ampoule and prevent further retraction of the sealing stopper; body fluid can now reach the ampoule via the bypass means in the shaft and across the spacing supports. In the case of recesses in the rear face of the sealing stopper, said stopper is retracted slightly during aspiration till against the front inner edge of the ampoule; body fluid can now reach the ampoule via the by-pass means in the shaft, the circumferential groove in the shaft and the recesses in the sealing stopper.

It will be obvious that the above provision can be used in all syringes provided they comprise a needle holder having a shaft which comprises a by-pass means for injection liquid and which, upon use of the syringe, can accommodate the sealing stopper. The present invention therefore also relates to a syringe for accommodating two different substances, said syringe comprising

- a separating stopper disposed in the ampoule in a sealing manner so as to keep two different sub-

stances separated from each other prior to use of the syringe, and

- an ampoule by-pass means formed in the wall of the ampoule, which by-pass means has a length slightly exceeding the length of the separating stopper and which by-pass means permits, during use of the syringe, liquid behind the separating stopper to reach the substance in front of the separating stopper and to mix with said substance or to dissolve it, but which ampoule by-pass means, prior to use of the syringe, is sealed from the liquid behind said separating stopper by means of said stopper.

In case the syringe of the invention is intended for separate storage of two different substances, such a syringe may accommodate two injection liquids. However, the use is not restricted hereto. The same syringe can also be used equally successfully to accommodate a solid medicament in the space between the sealing stopper and the separating stopper and a diluent or solvent therefor in the space behind the separating stopper. Such a syringe provides a great extent of flexibility so that the syringe can be used without any adapting means both for accommodating two or more different injection liquids and for accommodating a solid medicament and a solvent or diluent for said medicament. In particular for this application the use of a needle guard with bacteria filter offers the advantage, that during the operation of dissolving the solid medicament in the solvent the syringe remains sterile, because the needle guard does not need to be removed beforehand. Such a two-chamber syringe can be filled very simply by first providing the sealing stopper and then providing, in a vertical position, successively the first injection liquid, the separating stopper, the second injection liquid, and finally the plunger. Of course, the reverse sequence is equally possible. After providing the needle holder comprising or not comprising an injection needle, preferably covered by a needle guard, and the finger grip, the syringe is ready for delivery to the customer. This filling procedure presents the opportunity to accommodate without any problems a freeze-dried medicament in the front compartment and a solvent or diluent for said medicament in the rear compartment.

The by-pass means in the wall of the ampoule may be constructed in various manners. The ampoule may be made of glass or of a suitable synthetic material; in the latter case the ampoule may be manufactured, for example, by injection moulding. When the ampoule is made of synthetic material the by-pass means in the wall of the ampoule preferably consists of at least one groove recessed in the inner wall of the ampoule and extending in the longitudinal direction of the ampoule over a length which is slightly larger than the length of the separating stopper of the collective separating stoppers. In another preferred embodiment the inner wall of the ampoule at the area of the

by-pass comprises at least one ridge which extends in the longitudinal direction of the ampoule over a length which is slightly larger than the length of the separating stopper or the collective separating stoppers, so that the separating stopper or stoppers, during use of the syringe, is/are deformed by contact with the ridge or ridges, a passage for the liquid behind the separating stopper or stoppers being formed through which the liquid can pass said stopper or stoppers. Such by-pass means may also be made in a glass ampoule wall, but synthetic materials are better suited for this purpose. A glass ampoule is by far to be preferred to a synthetic material ampoule because no diffusion of air oxygen to the substances accommodated in the ampoule can occur through the glass wall so that oxidative decomposition of the said substances is avoided. Moreover, synthetic materials are generally less suitable than glass to store therein for a longer period of time liquids destined for injection, because synthetic materials can contaminate the liquids or can adversely influence the stability of the said liquids. In a glass ampoule, the wall of the ampoule can most simply be provided with a by-pass means by deforming the wall of the ampoule at the area of the by-pass over a length which is slightly larger than the length of the separating stopper or collective separating stoppers, so that, upon use of the syringe, the liquid behind the separating stopper or stoppers can pass said stopper or stoppers at the area of the deformation. Such a deformation of the ampoule wall may be in the form as shown in the United States Patent Specification 2,717,601. For example, the local deformation of the ampoule wall consists preferably of at least one outwardly projecting longitudinal bulge of the ampoule wall, so that upon use of the syringe, the liquid behind the separating stopper or stoppers can reach the substance in front of the separating stoppers or front separating stopper, or of at least one inwardly projecting longitudinal bulge of the ampoule wall so that, upon use of the syringe, the separating stopper or stoppers is/are deformed by contact with the inwardly projecting bulge or bulges, a passage for the liquid behind the separating stopper or stoppers being formed allowing the liquid to reach the substance in front of the separating stopper or front separating stopper past said stopper or stoppers. The ampoule wall may also be deformed locally in such way that the ampoule has an oval cross-section at that area so that, upon use of the syringe, the liquid behind the separating stopper or stoppers can reach the substance in front of the separating stopper or front separating stopper.

A local deformation of the wall of the ampoule in the form of one or more outwardly projecting longitudinal bulges is generally considered to be the best suitable solution for a by-pass means in the glass ampoule wall, because it can be very simply provided in an ampoule wall and, upon use of the syringe, forms a reliable passage for the liquid. The needle holder

provided with a collar ensures, together with the finger grip, that such a bulge or such bulges in the glass ampoule wall is/are protected from damage or fracture. For example, when the syringe is dropped on a table or on the floor, it will now in most of the cases land on the needle holder collar and finger grip projecting beyond the ampoule wall, so that the bulge in the ampoule wall cannot contact the table or the floor. Moreover, packaging such syringes is easier, and during transport of the packaged syringes fractures will less easily occur due to the protecting influence of the needle holder collar and the finger grip. A syringe without a needle holder, as described in the United States Patent Specification 2,717,601 mentioned hereinbefore lacks such a protection of the by-pass means in the glass wall of the ampoule. It will be obvious that the invention relates more in particular to pre-fillable or pre-filled syringes, i.e. syringes which can be filled by the customer or supplier ample time before use.

The components of the syringe, such as ampoule, needle guard, finger grip and plunger rod, can be connected in the usual manner, for example, by means of a screwed joint, bayonet or snap-cap connection. The injection needle is preferably covered by a needle guard to keep the needle in a sterile condition. In case the injection needle is supplied separately, the needle holder neck is preferably constructed externally as a cone, for example, a Luer cone or Luer lock cone, around which the needle comprising a needle sleeve can be connected in a fitting manner. Usually said neck is sealingly provided with a detachable cap to keep the contents of the syringe sterile before use. Said cap is preferably also provided with a bacteria filter to keep the syringe sterile even during and after the mixing operation. Needle holder, finger grip and plunger rod are preferably manufactured from a suitable non-deformable synthetic material, the stoppers from a suitable resilient material, preferably rubber of a pharmaceutical quality.

The invention will now be described in greater detail with reference to an embodiment which is shown in the drawings, in which:

Figure 1 is a longitudinal sectional view of a syringe according to the invention in the condition in which it can be transported and stored;

Figures 2 and 3 are cross-sectional views through the needle holder and ampoule respectively of the Figure 1 syringe, taken on the lines II-II and III-III viewed in the direction of the needle and of the plunger, respectively; and

Figure 4 is a bottom view of the sealing stopper of the Figure 1 syringe, viewed in the direction of the injection needle.

The syringe shown in Figure 1 comprises an ampoule 11, in which at one end a plunger 12 is provided while the other end comprises a needle holder 13 in the neck 14 of which an injection needle 15 is connect-

ed. The injection needle is covered in a sterile manner by a needle guard 16 which at its front comprises an aperture with a bacteria filter 17. The plunger can be moved by means of a plunger rod 18 which is connected to the plunger, for example, by means of a screwed joint. At the same end where the plunger is present, the ampoule comprises on its outside a finger grip 19 which is connected around the ampoule according to the so-called snap-cap principle. The ampoule is preferably manufactured from glass, the finger grip preferably from a slightly resilient but non-deformable material, for example, a synthetic material. In another suitable embodiment the finger grip forms one assembly with the ampoule and may then be formed as a flange-like part of the ampoule projecting radially outwards.

Instead of a needle guard with bacteria filter, a needle guard which is closed entirely at its front end may alternatively be used. The use of a needle guard with bacteria filter is to be preferred, however, because in this case the needle can remain protected in a sterile manner for a longer period of time, namely during mixing and de-aerating. Moreover the syringe then may be stored an additional period after the mixing or making ready for use operation before it is actually used.

A sealing stopper 20 is present in the part of the ampoule remote from the plunger at a considerable distance from the open end of the ampoule. Two different liquids 21 and 22 which are kept separated from each other by a separating stopper 23 are present in the ampoule between the plunger and the stopper. The stoppers are manufactured from rubber of a pharmaceutical quality. The ampoule furthermore comprises a by-pass means for the injection liquid in the form of a longitudinal bulge 24 in the glass wall, as a result of which a longitudinal slot-shaped aperture is formed. This slot-shaped aperture terminates at its rear end near separating stopper 23, so that the injection liquids in the stored condition of the syringe cannot reach each other.

The by-pass means in the ampoule wall may also be constructed differently. For example, the glass wall may locally be bent inwards longitudinally, so that internally at the area of the passage a longitudinal ridge is formed in the ampoule. The said ridge can cause the separating stopper to be deformed upon contacting, so that on either side of the ridge passages for the liquid are formed. Of course, two or more slot-shaped apertures or ridges may also be present. The wall of the glass ampoule at the area of the by-pass may also have an oval cross-section allowing liquid to pass the stopper in the passage.

The needle holder 13 comprising a neck 14 is connected to the ampoule by means of a collar 25. A shaft 26 is present between the neck and the collar. The needle holder is preferably manufactured from a slightly resilient material which, however, has suffi-

cient non-deformability, for example, a suitable synthetic material, and is connected to the front end of the ampoule by means of a so-called snap-cap connection. In another embodiment the needle holder may be connected to the ampoule by means of a screwed or a bayonet connection, or, when the ampoule also comprises a collar or a flange, by means of a clamping ring. Four slots 27 are recessed in the inner wall of the shaft and the rear face of the neck and communicate with the injection needle. The collective cross-section of the slots should at least be as large as that of the duct in the injection needle. The shaft of the needle holder is constructed in such way that when the sealing stopper is moved forward axially, it is received by the shaft in a sliding manner. The inner wall of the shaft, therefore, has a slightly larger circumference than the inner wall of the ampoule; however, this circumference may not be larger than the circumference of the sealing stopper in the expanded condition. The inner wall of the shaft is slightly longer than the length of the sealing stopper so that the part 28 of the slots adjoining the ampoule is uncovered when the sealing stopper is moved in its extreme forward position to against the rear face of the neck of the needle holder.

In order to be able for nurse-aspiration, the rear face of the sealing stopper comprises three notches 29 (see also figure 4) which are recessed in the circumferential edge of the sealing stopper, while a circumferential groove 30 which communicates with the slots 27 in the shaft of the needle holder is recessed in the part of the shaft of the needle holder adjoining the ampoule. The operation of these provisions upon nurse-aspiration has been explained already hereinbefore.

The use of the syringe according to the invention is described in parent application EP-A-0207544 (86200983.4). Nurse-aspiration may be carried out, if desired, the notches 29 recessed in the circumferential edge of the rear face of the sealing stopper 20 ensuring that the admission of body fluid to the ampoule cannot be obstructed when during said nurse-aspiration the sealing stopper is slightly retracted into the shaft of the needle holder.

Claims

1. A syringe, comprising:

- a hollow, substantially cylindrical ampoule (11) which is open at both ends,
- a plunger (12) which is movable in the ampoule and seals said ampoule and to which a plunger rod (18) is connectable,
- a substantially rotationally symmetrical sealing stopper (20) having such dimensions that the sealing stopper can be provided in a sealing manner in said ampoule and so as to be

movable in the ampoule,

- a finger grip (19) or means for the connection thereof to the outside of the ampoule, and

- a needle holder (13) comprising:

(a) a collar (25) connected to the front end of the ampoule in a sealing manner,

(b) a neck (14) for sealingly attaching an injection needle (15), optionally covered by a needle guard (16) to keep the needle in a sterile condition,

(c) a hollow, substantially cylindrical shaft (26) disposed between the collar and the neck, the shaft being proportioned so that the space bounded by the inner wall of the shaft and the rear face of the neck has a slightly larger circumference than the inner wall of the ampoule and is at least longer than the sealing stopper, and

(d) a needle holder by-pass means (27) in the inner wall of the shaft through which injection liquid (21, 22) behind the sealing stopper can reach the injection needle when, upon using the syringe, the sealing stopper is moved forward into the shaft of the needle holder,

said syringe being characterized in that

- the rear face of the sealing stopper (20) comprises a plurality of recesses (29) which are provided in the circumferential edge of the sealing stopper, and

- a circumferential groove (30), communicating with the needle holder by-pass means (27), is recessed in the backmost portion of the shaft of the needle holder adjoining the ampoule,

so that during nurse aspiration, when the sealing stopper is positioned with its rear edge bearing against the front end of the ampoule, the recesses (29) communicate with the circumferential groove (30).

2. A syringe, comprising:

- a hollow, substantially cylindrical ampoule (11) which is open at both ends,

- a plunger (12) which is movable in the ampoule and seals said ampoule and to which a plunger rod (18) is connectable,

- a substantially rotationally symmetrical sealing stopper (20) having such dimensions that the sealing stopper can be provided in a sealing manner in said ampoule and so as to be movable in the ampoule,

- a finger grip (19) or means for the connection thereof to the outside of the ampoule, and

- a needle holder (13) comprising:

(a) a collar (25) connected to the front end of the ampoule in a sealing manner,

(b) a neck (14) for sealingly attaching an in-

jection needle (15), optionally covered by a needle guard (16) to keep the needle in a sterile condition,

(c) a hollow, substantially cylindrical shaft (26) disposed between the collar and the neck, the shaft being proportioned so that the space bounded by the inner wall of the shaft and the rear face of the neck has a slightly larger circumference than the inner wall of the ampoule and is at least longer than the sealing stopper, and

(d) a needle holder by-pass means (27) in the inner wall of the shaft through which injection liquid (21, 22) behind the sealing stopper can reach the injection needle when, upon using the syringe, the sealing stopper is moved forward into the shaft of the needle holder,

said syringe being characterized in that the rear face of the sealing stopper comprises a plurality of spacing supports, which extend backwards and are provided on the circumferential edge of the sealing stopper in a mutually spaced position, and which are so proportioned, that during nurse aspiration, when the spacing supports bear against the front end of the ampoule, body fluid can pass the sealing stopper backwards through the needle holder bypass means and the spaces between said supports mutually.

3. A syringe according to Claim 1 or 2 for accommodating two different substances, said syringe comprising:

- a separating stopper (23) disposed in the ampoule (11) in a sealing manner so as to keep said different substances (21, 22) separated from each other prior to use of the syringe, and

- an ampoule by-pass means (24) formed in the wall of the ampoule, which by-pass means has a length slightly exceeding the length of the separating stopper (23) and which by-pass means permits, during use of the syringe, liquid (22) behind the separating stopper to reach the substance (21) in front of the separating stopper and to mix with said substance or to dissolve it, but which ampoule by-pass means, prior to use of the syringe, is sealed from the liquid behind said separating stopper by means of said stopper.

Patentansprüche

1. Spritze mit:

- einer hohlen, im wesentlichen zylindrischen Ampulle (11), die an beiden Enden offen ist,
- einem Kolben (12), der in der Ampulle be-

wegbar ist und die Ampulle dicht abschließt, und mit dem eine Kolbenstange (18) verbindbar ist,

- einem im wesentlichen rotationssymmetrischen Dichtstopfen (20) mit derartigen Abmessungen, daß er dichtend in der Ampulle vorgesehen werden kann und in der Ampulle bewegbar ist,

- einem Fingergriff (19) oder Mitteln zu dessen Verbindung mit der Außenseite der Ampulle, und

- einem Nadelhalter (13), welcher:

(a) einen Kragen (25), der mit dem vorderen Ende der Ampulle dicht verbunden ist, (b) einen Hals (14) zum dichten Befestigen einer Injektionsnadel (15), gegebenenfalls unter Abdeckung durch einen Nadelschutz (16), um die Nadel in sterilem Zustand zu halten,

(c) einen hohlen, im wesentlichen zylindrischen Schaft (26), der zwischen dem Kragen und dem Hals angeordnet ist, wobei der Schaft so bemessen ist, daß der von der Innenwand des Schaftes und der Rückseite des Halses begrenzte Raum einen etwas größeren Umfang als die Innenwand der Ampulle hat und zumindest länger als der Dichtstopfen ist, und

(d) eine Nadelhalter-Bypaßeinrichtung (27) in der Innenwand des Schaftes aufweist, durch die Injektionsflüssigkeit (21, 22) hinter dem Dichtstopfen die Injektionsnadel erreichen kann, wenn bei Gebrauch der Spritze der Dichtstopfen nach vorne in den Schaft des Nadelhalters bewegt wird, welche Spritze dadurch gekennzeichnet ist, daß

- die Rückseite des Dichtstopfens (20) eine Mehrzahl von Ausnehmungen (29) aufweist, die im Umfangsrand des Dichtstopfens vorgesehen sind, und

- eine Umfangsnut (30), die mit der Nadelhalter-Bypaßeinrichtung (27) in Verbindung steht, im hintersten Abschnitt des Schaftes des Nadelhalters ausgenommen ist, der an die Ampulle anschließt, so daß während eines Aufzieh-Ansaugens, wenn der Dichtstopfen in einer Position mit seinem hinteren Rand in Anlage am vorderen Ende der Ampulle vorliegt, die Ausnehmungen (29) mit der Umfangsnut (30) in Verbindung stehen.

2. Spritze mit:

- einer hohlen, im wesentlichen zylindrischen Ampulle (11), die an beiden Enden offen ist, - einem Kolben (12), der in der Ampulle bewegbar ist und die Ampulle dicht abschließt, und mit dem eine Kolbenstange (18) verbind-

bar ist,

- einem im wesentlichen rotationssymmetrischen Dichtstopfen (20) mit derartigen Abmessungen, daß er dichtend in der Ampulle vorgesehen werden kann und in der Ampulle bewegbar ist,

- einem Fingergriff (19) oder Mitteln zu dessen Verbindung mit der Außenseite der Ampulle, und

- einem Nadelhalter (13), welcher:

(a) einen Kragen (25), der mit dem vorderen Ende der Ampulle dicht verbunden ist, (b) einen Hals (14) zum dichten Befestigen einer Injektionsnadel (15), gegebenenfalls unter Abdeckung durch einen Nadelschutz (16), um die Nadel in sterilem Zustand zu halten,

(c) einen hohlen, im wesentlichen zylindrischen Schaft (26), der zwischen dem Kragen und dem Hals angeordnet ist, wobei der Schaft so bemessen ist, daß der von der Innenwand des Schaftes und der Rückseite des Halses begrenzte Raum einen etwas größeren Umfang als die Innenwand der Ampulle hat und zumindest länger als der Dichtstopfen ist, und

(d) eine Nadelhalter-Bypaßeinrichtung (27) in der Innenwand des Schaftes aufweist, durch die Injektionsflüssigkeit (21, 22) hinter dem Dichtstopfen die Injektionsnadel erreichen kann, wenn bei Gebrauch der Spritze der Dichtstopfen nach vorne in den Schaft des Nadelhalters bewegt wird,

welche Spritze dadurch gekennzeichnet ist, daß die Rückseite des Dichtstopfens eine Mehrzahl von Distanzhaltern aufweist, die sich nach hinten erstrecken und am Umfangsrand des Dichtstopfens in gegenseitig beabstandeter Position vorgesehen sind, und die so bemessen sind, daß während eines Aufzieh-Ansaugens, wenn die Distanzhalter gegen das vordere Ende der Ampulle anliegen, Körperflüssigkeit am Dichtstopfen vorbei nach hinten durch die Nadelhalter-Bypaßeinrichtung und die Räume zwischen den jeweiligen Haltern strömen kann.

3. Spritze nach Anspruch 1 oder 2, zur Aufnahme von zwei verschiedenen Substanzen, wobei die Spritze:

- einen Trennstopfen (23), der in der Ampulle (11) dichtend angeordnet ist, um die verschiedenen Substanzen (21, 22) vor dem Gebrauch der Spritze voneinander getrennt zu halten, und

- eine Ampullen-Bypaßeinrichtung (24) aufweist, die in der Wand der Ampulle geformt ist, welche Bypaßeinrichtung eine Länge hat, die etwas größer als jene des Trennstopfens (23)

ist, und durch welche Bypaßeinrichtung während des Gebrauchs der Spritze Flüssigkeit (22) hinter dem Trennstopfen die Substanz (21) vor dem Trennstopfen erreichen und sich mit der Substanz mischen oder sie lösen kann, welche Ampullen-Bypaßeinrichtung jedoch vor dem Gebrauch der Spritze von der Flüssigkeit, die hinter dem Trennstopfen vorhanden ist, mit Hilfe des Trennstopfens abgedichtet ist.

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Revendications

1. Une seringue, comprenant:

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- un corps creux, sensiblement cylindrique (11), ouvert aux deux extrémités,
- un piston plongeur (12) mobile dans le corps de seringue et assurant l'étanchéité dudit corps, sur lequel peut être fixé une tige de piston (18),
- un bouchon obturateur, monté à rotation sensiblement symétrique (20), dimensionné de telle sorte que le bouchon obturateur peut être monté de façon étanche dans ledit corps, et de façon mobile dans le corps.

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- des moyens de prise pour les doigts (19) ou des moyens pour les fixer à l'extérieur du corps, et

- un porte-aiguille (13), comprenant:

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- (a) un collet (25), fixé sur l'extrémité avant du corps de seringue de façon étanche,
- (b) un cône (14) pour le montage de façon étanche d'une aiguille d'injection (15), éventuellement recouverte d'un capuchon d'aiguille (16) pour maintenir l'aiguille à l'état stérile,

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- (c) un embout creux, sensiblement cylindrique (26), disposé entre le collet et le cône, l'embout étant dimensionné de manière que la circonférence de l'espace défini par la paroi intérieure de l'embout et la face arrière du cône soit légèrement supérieure à la paroi intérieure du corps de seringue et que sa longueur soit au moins égale à celle du bouchon obturateur, et

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- (d) des moyens de bypass ou de dérivation de porte-aiguille (27) ménagés dans la paroi intérieure de l'embout, à travers lesquels le liquide d'injection (21, 22) se trouvant derrière le bouchon obturateur, peut parvenir à l'aiguille d'injection lorsque le bouchon obturateur est avancé dans l'embout de porte-aiguille lors de l'utilisation de la seringue,

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ladite seringue étant caractérisée en ce que

- la face arrière du bouchon obturateur (20) comprend une pluralité de cavités (29) ménagées

dans le bord circonférentiel du bouchon obturateur, et

- qu'une rainure circonférentielle (30), communiquant avec les moyens de bypass de porte-aiguille (27) est ménagée dans la partie arrière de l'embout de porte-aiguille adjacente au corps de seringue, de manière que lors d'une manoeuvre d'aspiration ou de pompage effectuée par l'infirmière, lorsque le bouchon obturateur est disposé de manière que son bord arrière porte contre l'extrémité avant du corps de seringue, les cavités (29) communiquent avec la rainure circonférentielle (30).

2. Une seringue, comprenant:

- un corps de seringue creux, sensiblement cylindrique (11), ouvert aux deux extrémités,
- un piston plongeur (12) mobile dans le corps de seringue et assurant l'étanchéité dudit corps auquel peut être fixée une tige de piston (18),

- un bouchon obturateur, monté à rotation sensiblement symétrique (20), dimensionné de telle sorte que ledit bouchon obturateur peut être monté de façon étanche dans ledit corps de seringue, et de façon mobile dans le corps,

- des moyens de prise pour les doigts (19) ou des moyens pour les fixer à l'extérieur du corps, et

- un porte-aiguille (13), comprenant:

- (a) un collet (25), fixé sur l'extrémité avant du corps de façon étanche,

- (b) un cône (14) pour le montage de façon étanche d'une aiguille d'injection (15), éventuellement recouvert d'un capuchon d'aiguille (16) pour le maintien de l'aiguille à l'état stérile,

- (c) un embout creux, sensiblement cylindrique (26), disposé entre le collet et le cône, l'embout étant dimensionné de manière que la circonférence de l'espace défini par la paroi intérieure de l'embout et la face arrière du cône soit légèrement supérieure à celle de la paroi intérieure du corps de seringue et que sa longueur soit au moins égale à celle du bouchon obturateur, et

- (d) des moyens de bypass ou de dérivation de porte-aiguille (27) ménagés dans la paroi intérieure de l'embout, à travers lesquels le liquide d'injection (21, 22) se trouvant derrière le bouchon obturateur, peut parvenir à l'aiguille d'injection lorsque le bouchon obturateur est avancé dans l'embout de porte-aiguille lors de l'utilisation de la seringue,

ladite seringue étant caractérisée en ce que la face arrière du bouchon obturateur (20) comprend une pluralité de supports d'entretoisement, dirigés vers l'arrière et ménagés sur le bord circonférentiel du bouchon obturateur, en position espacée les uns par rapport aux autres, et disposés de manière que lors d'une manoeuvre d'aspiration ou de pompage effectuée par l'infirmière, lorsque les supports d'entretoisement portent contre l'extrémité avant du corps de seringue, le fluide corporel peut traverser le bouchon obturateur vers l'arrière, à travers les moyens de bypass de porte-aiguille et les intervalles entre lesdits supports.

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3. Une seringue selon la revendication 1 ou 2, prévue pour recevoir deux substances différentes, ladite seringue comprenant:

- un bouchon de séparation (23) disposé dans le corps de seringue (11) de façon étanche, de manière à conserver lesdites substances différentes (21,22) séparées l'une de l'autre avant l'utilisation de la seringue, et

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- des moyens de bypass ou de dérivation de corps de seringue (24) ménagés dans la paroi du corps de seringue, la longueur desdits moyens de bypass étant légèrement supérieure à la longueur du bouchon de séparation (23), et lesdits moyens de bypass, lors de l'utilisation de la seringue, permettant au liquide (22) se trouvant derrière le bouchon de séparation, d'atteindre la substance (21) située à l'avant du bouchon de séparation et de se mélanger avec ladite substance ou de la dissoudre, tandis qu'avant l'utilisation de la seringue, l'étanchéité desdits moyens de bypass de corps de seringue par rapport au liquide se trouvant derrière ledit bouchon de séparation est assurée à l'aide dudit bouchon.

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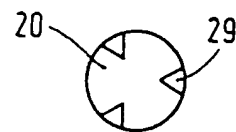
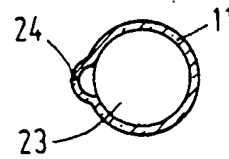
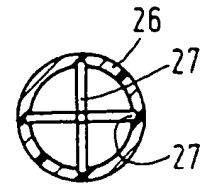
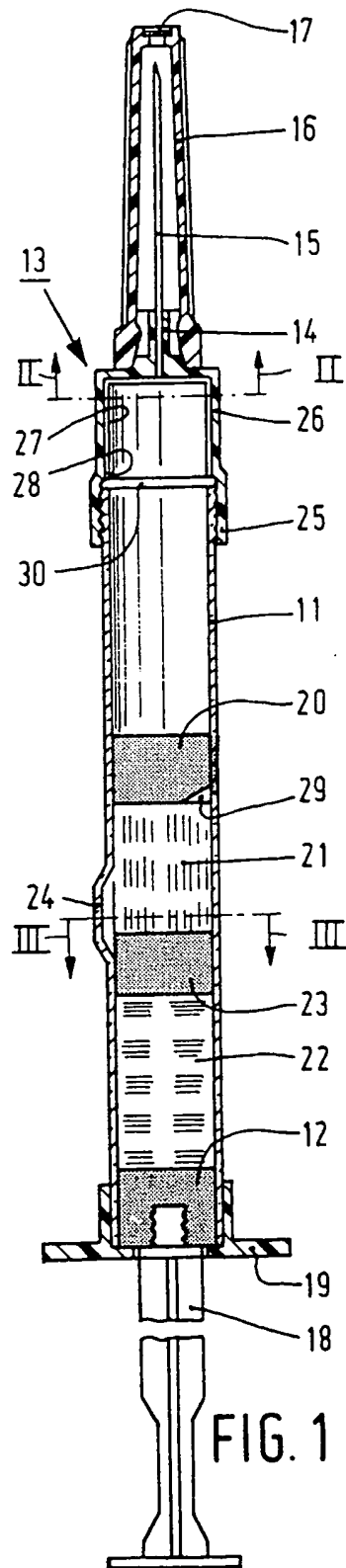
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